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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,013	04/28/2005	Koushi Nakano	SAEG153.002APC	1676
20995 7590 05/15/2008 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614				
EXAMINER NOBLE, MARCIA STEPHENS				
ART UNIT		PAPER NUMBER		
1632				
NOTIFICATION DATE		DELIVERY MODE		
05/15/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary

Application No.

10/533,013

Applicant(s)

NAKANO ET AL.

Examiner

MARCIA S. NOBLE

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 13-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of Claims

1. Claims 1-20, 24, and 25 are pending. Claim 1 is amended by Applicant's response, filed 2/28/2008.

Election/Restrictions

2. Claims 13-20, 24, and 25 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/18/2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (of record; 2000), Keetch et al (of record, 1994), Fulmer et al (of record; 2000), Robinette (of record, 1988), and Royston D (Acta anaesthesiologica Scandinavica 30(7):abstract, 1986), in view of Goto (of record; 1988).

Applicant traverses this rejection. Applicant's arguments filed 2/21/2008 have been fully considered but they are not persuasive.

Applicant asserts that none of the arts teach an abacterial prostatitis animal model that has prostatic tissue damage but does not have tissue damage in urethral or bladder tissues (p. 7, par 2). Applicant asserts that Lang et al teaches that 3 of 5 animals died before the 7th day post-treatment and that the animal models displayed substantial urethral and bladder tissue damage (referring to p. 203, col 1, top par of Lang; p. 7 par 3 of remarks). Applicant asserts that none of the other references provided teach a means to overcome the severe, typically lethal, amount of tissue damage incurred when practicing the methods of Lang and therefore would teach in a abacterial prostatitis model that does not have urethral and bladder tissue damage, as claimed (p. 7, last par).

Applicant's interpretation of Lang et al is not fully correct. On page 203, col 1, top par), Lang et al recite, "Three of the five test animals suffered severe prostatic inflammation and prostatic urethral occlusion, resulting in acute urinary retention and

death." "Urethral occlusion" can be caused by urethral damage or can be a result of prostatic tissue damage and cellular shearing into the urethra. Therefore, "urethral occlusion" in itself does not demonstrate urethral tissue damage in itself. It only suggests that for some undefined source, the urethra is blocked. In terms of "urinary retention", this characteristic is not different from the model disclosed by the specification which suggests that following HCl treatment animal models have increased urinary retention (see paragraph bridging p. 45 -46 of the specification). Furthermore, again, urinary retention, in itself, does not demonstrate bladder tissue damage. Therefore, contrary to Applicant's assertion, Lang et al does not definitively demonstrate tissue damage to the urethra or bladder in their prostatitis models.

Examiner still asserts that the instant invention would be obvious over the art because Lang et al and other disclosed demonstrate that several non-specific irritants have been used in the art to make prostatitis animal models. Robinette establishes that HCl is an example of a non-specific irritant that has been used to cause an abacterial inflammatory response in an organ in the art. Goto establishes that HCl had been used in the process of making a prostatitis model mouse. Therefore, given a finite number of predictable inflammatory agents, an artisan would have a reasonable expectation of success in producing an abacterial prostatitis model when injecting HCl into the prostate.

Applicant asserts that art of Lang and other would not reasonably lead to a prostatitis model that prostate tissue damage but no urethral and bladder damage. Examiner does not agree. As discussed previously in prosecution, HCl is well

established in the art as a non-specific irritant, as exemplified in Robinette. As a non-specific irritant, its damaging effects are reliant upon the concentration of the irritant present in the issue, with high concentrations resulting in higher and more extensive tissue involvement. This is supported by the art of Keetch et al which demonstrates that higher concentrations of irritant resulted in greater tissue involvement and greater inflammation (p. 248, col 1, par 2). Therefore, an artisan of ordinary skill would know that the level of tissue damage and involvement of other tissue such as the neighboring tissues of the urethra and bladder, is titratable. Therefore, an artisan would know that using lower concentrations of a non-specific irritant would limit and localize the damages to the prostate with routine experimentation. This is in line with the teachings of the specification which suggestteaches that the level of urethral and bladder damage and dysfunction is titratable (par bridging p. 42 and 43) or the specification. Therefore, because it is well-established in the art that the damages caused by a non-specific inflammatory agent are titratable, it is within the routine skill of the art for an artisan to establish a prostatitis model that comprises prostate inflammation without bladder and urethral damage, as claimed.

Therefore, because Applicant's arguments are not found persuasive and the amendments to the claims are still within the teachings of the art, the instant obviousness rejection is maintained.

4. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch, Ph.D./
Primary Examiner, Art Unit 1632

Marcia S. Noble
AU 1632